

EXHIBIT D

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

**IN RE ETHICON, INC., PELVIC REPAIR
SYSTEM PRODUCTS LIABILITY
LITIGATION** : **CIVIL ACTION NO.**
: **2:12-md-02327**
: **MDL No. 2327**

This Document Applies To:

Mullins, et al. vs. Ethicon, Inc., et al., 2:12-cv-
02952, and each of the consolidated cases
identified in Exhibit A to Plaintiffs' Motion

:
: Judge Joseph R. Goodwin
:
:

**REPLY MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION
TO EXCLUDE THE OPINIONS OF DR. REBECCA M. RYDER**

In further support of their Motion to Exclude the Opinions of Dr. Rebecca M. Ryder
("Dr. Ryder"), Plaintiffs state as follows:

ARGUMENT

I. Dr. Ryder's deficient "reliance" list should serve to exclude her opinions.

As Plaintiffs point out in their opening brief, after being presented with a document that she purported "relied" upon but admitted that she had never seen before, Dr. Ryder conceded that she did not verify that she had read all of the documents that Ethicon chose to include on her reliance list. Ex. E to Pltfs.' Motion, Dr. Rebecca Ryder 7/11/16 Dep. Tr. ("Ryder 7/11/16 Dep. Tr.") at 70:16-71:6. Ethicon would have the Court believe that this is just a coincidence. But this document—which directly relates to her (unsupported) opinion about mechanically cut versus laser cut mesh (discussed below)—was one of the few Ethicon documents presented to Dr. Ryder during her deposition. *Id.* at 70:7-11.

Allowing Dr. Ryder to include documents she's never reviewed on her reliance list, only to later deny any knowledge of them and refuse to discuss them at her deposition or trial, prevents Plaintiffs the opportunity to test Dr. Ryder's opinions on cross-examination. Her opinions should be excluded under Federal Rule of Civil Procedure 26. *See* Fed. R. Civ. P. 26(a)(2)(B)(i) and (ii) (requiring disclosure of an expert's opinions, including the basis for such opinions, and the facts or data considered by the witness in forming such opinions).

II. Opinions Regarding Defective Design

In her report, Dr. Ryder opined that the TVT "is not defectively designed." Ex. B to Pltfs.' Motion at 30. In its response brief, Ethicon argues that Dr. Ryder need not have "experience in device design" in order to render an opinion on the "risks and benefits of the TVT." Defs.' Br. at 4-5. But that is not the issue. Plaintiffs are well aware that this Court has allowed expert physicians to discuss the risks and benefits of medical devices based upon their clinical experience. However, Dr. Ryder's opinion is not limited to knowledge that she could gain from her clinical experience—such as the "risks and benefits" or the "safety and effectiveness" of the TVT (like the testimony in the cases Ethicon cites). Dr. Ryder seeks to offer an opinion that the device was "not defectively designed." But as this Court has held (in one of the cases cited in Ethicon's brief): "An expert may not state [her] opinion using 'legal terms of art,' such as 'defective,' 'unreasonably dangerous,' or 'proximate cause.' *Wilkerson v. Boston Sci. Corp.*, 2015 U.S. Dist. LEXIS 58671 (S.D. W. Va. May 5, 2015). Regardless of Dr. Ryder's clinical experience, she is not an expert on device design and her ultimate opinions on that issue—as opposed to her testimony about her own experiences and understanding of the risks and benefits of the TVT—should be excluded.

III. Opinions Regarding Polypropylene Mesh Material, Mesh Pore Size, And Risk of Infection

Plaintiffs argued that Dr. Ryder’s opinions regarding the polypropylene material, mesh pore size, and risk of infection of the TVT must be excluded because they are unreliable, baseless, and she is not qualified to render them. In response, Ethicon cites to a few cases where the Court has allowed expert physicians to testify generally regarding their own experience with the mesh devices. Defs.’ Br. at 7-8. Ethicon misconstrues the issue, as again, Dr. Ryder’s opinions are not limited to her own experience and she seeks to opine on matters that she cannot possibly know about from her clinical experience alone. More specifically, Dr. Ryder seeks to opine that the TVT’s “pore size is sufficiently large” and that the polypropylene mesh does not present “increased risks of infection.” Ex. B to Pltfs.’ Mem., Ryder Expert Report op. 2, at 30. These are general pronouncements about the sufficiency of specific technical characteristics of the material and design of the TVT—they are not simply her own experiences using the mesh. And while this Court has allowed experts to testify that they have not experienced a particular complication in their own practice—it has not permitted them to base broader conclusions on that limited experience. For example, this Court has previously rejected defense experts’ “I have not seen it, therefore it must not happen” opinions—holding: “[a]bsence of evidence is not evidence of absence.” *Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 583-85 (S.D. W. Va. 2014). Dr. Ryder seeks to provide similar testimony here. For example, because she claims to have not experienced—or noticed—problems relating to the pore size of the TVT mesh, she seeks to testify that it must be “sufficiently large.” And because she claims that she has not personally seen an increase in patients with infections, she seeks to testify that there is no “increased risk of infection.” Her opinions are no more reliable or helpful than those repeatedly excluded by this Court.

IV. Opinions regarding the differences, or “clinical significance” of mechanical cut mesh versus laser cut mesh should be excluded

Plaintiffs sought to exclude Dr. Ryder’s opinion that there is no difference in the safety or clinical outcomes between mechanically-cut and laser-cut mesh. Despite Ethicon’s protests to the contrary, this opinion still finds no support or basis in either Dr. Ryder’s clinical practice, or her review of the literature and evidence.

A. Dr. Ryder’s testimony proves that her clinical experience does not provide a reasonable basis for her to compare mechanically-cut and laser-cut mesh.

In their initial brief, Plaintiffs cited to—and quoted—Dr. Ryder’s admissions that: (1) she has *no idea* which of her patients were implanted with mechanically-cut mesh and which were implanted with laser-cut mesh; (2) she has not done a comparison of the complications or symptomology of the patients who have received the two types of mesh; (3) has no clinical data comparing the outcomes of patients with the two types of mesh. *See* Pltfs’ Br. at 7-9. But Ethicon still seeks to have the jury hear her opinions on how the two types of mesh compare. Similarly, Plaintiffs cited to admissions by Dr. Ryder that she: (1) does not have a reliable basis to publish her opinions on this issue; and (2) would not expect that other physicians would rely on her opinions when assessing the safety or effectiveness of the two types of mesh. *Id.* But Ethicon still maintains that her opinions are reliable enough to provide to a jury.

Ethicon’s arguments are far from convincing. Ethicon essentially ignores all of the testimony that Dr. Ryder gave at her deposition, and instead cites to this Court’s rulings that an expert physician need not “provide ‘exact statistics’ about the outcomes of patients.” Defs’ Br. at 9. But Plaintiffs were not requiring “exact statistics” at her deposition. Far from it, Plaintiffs were asking for the bare minimum from Dr. Ryder—but she still could not provide it. She does not know, in the most general sense possible, if or when she used mechanically cut mesh as

opposed to laser cut mesh, or if it had any effect on any patient's outcome. Given this complete lack of knowledge, record, or data, Ethicon cannot legitimately claim that Dr. Ryder's "clinical experience" should allow her to testify that there is no difference in the safety or clinical outcomes of the two types of mesh—the statement that she "never noticed a difference" is simply not enough. Defs' Br. at 9.

B. Dr. Ryder's review of the literature and/or Ethicon documents does not support any opinion regarding mechanical cut versus laser cut mesh.

As Ethicon states in its brief, Dr. Ryder seeks to testify that "[t]here's no evidence to suggest that the safety of TVT mesh is affected by whether it's mechanically cut or laser cut." Defs' Br. at 9. But there is. As Dr. Ryder herself admitted, that evidence is found in Ethicon's own internal documents. Pltfs' Br. at 10-11 (citing Ex. E to Pltfs.' Mem. at 63:16-64:16). Unfortunately, Dr. Ryder apparently has no familiarity with those documents; she could not discuss them at her deposition, and does not cite them in her report. *Id.* (citing Ex. E to Pltfs.' Mem. at 62:10-23 and 71:23-72:9). And when questioned about how her opinions are contradicted by Ethicon's own documents, Dr. Ryder simply claimed to have not seen the document (despite it being on her reliance list) and said she cannot comment on it. *Id.* (citing Ex. E to Pltfs.' Mem. at 69:12-70:9).

Ethicon claims to "disagree entirely with the significance of these internal documents." Defs.' Br. at 10. It is free to do so. But Dr. Ryder, as an expert, needs to provide a basis or a reason for her own disagreement. When given the chance to, however, she could not provide any sort of explanation of the documents or state why they do not support the fact that there is a difference between the two types of mesh. She simply claimed that she had not seen them, disagreed with them, but would not comment on them further.

Dr. Ryder's head in the sand approach cannot possibly render to a scientifically reliable opinion. Indeed, an expert's disagreement with contrary evidence without offering further explanation has previously been rejected by this Court.¹ Dr. Ryder cannot claim that there is "no evidence to suggest that the safety of TVT mesh is affected by whether it's mechanically cut or laser cut" when she simply choses to ignore the evidence that there is. Her opinions on the subject should be excluded in their entirety.

CONCLUSION

Ethicon, as the proponent of the expert testimony, bears the substantial burden of establishing that Dr. Ryder is sufficiently qualified and that the proposed testimony satisfies the applicable evidentiary standards for the admission of expert testimony. Considering the lack of experience, knowledge, and reliability inherent in the opinions discussed above, Ethicon cannot carry this burden and her testimony should be excluded.

Dated: August 22, 2016

Respectfully submitted,

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¹ See *Sanchez v. Boston Sci. Corp.*, No. 2:12-cv-05762, 2014 U.S. Dist. LEXIS 137189, *32-33 (S.D. W. Va. Sept. 29, 2014) ("[I]f the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable.").

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CERTIFICATE OF SERVICE

I hereby certify that on August 1, 2016, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

Respectfully submitted,

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